

DRAFT PANEL QUESTIONS

1. Identify the scientific questions that need to be addressed to demonstrate whether MUNJI devices are safe for multiple-patient use in the United States
2. Discuss the adequacy and feasibility of the currently available methods to assess the potential for cross contamination and the risk of disease transmission by MUNJI devices.
3. Feinman et al (1984) suggested that 10 pL is the minimum amount of blood that can transmit HBV in chimpanzees. However, this suggestion is only based on a single animal study and there is no recognized amount of blood that can transmit HBV.

Considering the public health need for MUNJIs, discuss whether there is evidence to support a maximum amount of residual blood on a MUNJI that would be considered a clinically acceptable risk. If so, discuss the level of residual blood that could be considered a clinically acceptable risk.

4. Do MUNJIs present an unreasonable and substantial risk of health hazard or injury that cannot be, or has not been, addressed by labeling, such as modifications to the Indications for Use or restrictions of use?